Notice of Allowability	Application No.	Applicant(s)	
	09/760,819	STANLEY, CHRISTOPHER J.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *3/29/3007*.

2. ☒ The allowed claim(s) is/are *, 3-17, 20, 23, 25, 26, 28-33, and 35-38* .

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *5/2007* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

EXAMINER'S AMENDMENTS

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Peng Chen (Reg. No. 43,543) on May 10, 2007.

2. The application has been amended as follows:

In the claims:

1. (Currently Amended): A process for [the] amplification of a nucleic acid template comprising:

providing a primer covalently bound to a non-nucleotide carrier macromolecule;

hybridizing the bound primer to said template; [and]

extending said bound primer to form an extended primer which replicates from said template,

wherein said carrier macromolecule is a dextran that is water soluble at a temperature in the range of 0-60°C and has a peak molecular weight in the range of about 1,000 to about 40,000,000 Daltons; and

performing amplification of the nucleic acid template.

3. (Currently Amended): A process for [the] amplification of a nucleic acid template comprising:

providing a first primer bound to a non-nucleotide carrier macromolecule via one or more moieties derived from divinyl sulfone located on the non-nucleotide carrier macromolecule;

hybridizing the bound first primer to said template; [and]

extending said bound first primer to form an extended primer which replicates from said template;

wherein the non-nucleotide carrier macromolecule is a dextran; and

performing amplification of the nucleic acid template.

4. (Currently Amended): The process as claimed in claim 3, wherein the non-nucleotide carrier macromolecule in its free state is substantially linear and substantially uncharged at a pH in the range of 4 to 10.

6. (Currently Amended): The process as claimed in claim 3, wherein said non-nucleotide carrier macromolecule is water soluble and has a molecular weight in excess of 80,000 Daltons.

7. (Currently Amended): The process as claimed in claim 3, wherein said first primer is bound to said non-nucleotide carrier macromolecule by a covalent linkage formed between one of the two vinyl groups of the divinyl sulphone [and a reactive functionality] on the non-nucleotide carrier macromolecule[, and

by a covalent linkage formed between one of the two vinyl groups of the divinyl sulphone] and a reactive [functionality] group on the first primer.

8. (Currently Amended): The process as claimed in claim 3, wherein said first primer is extended by a polymerase wherein said polymerase incorporates nucleotides into said first primer.

10. (Currently Amended): The process as claimed in claim 6, further comprising hybridizing at least two other primers to said template wherein said first primer is extended by the action of a ligase sequentially ligating said first primer to the at least two other primers hybridised to said template.

11. (Currently Amended): The process as claimed in claim 3, wherein said template is a double stranded template and is denatured to a single stranded form, said [carrier macromolecule-] bound first primer is complementary in sequence to a region of one of the template strands and a second primer is provided which is complementary in sequence to a region of the other strand of the template, [which] and the second primer is also extended [so as] to form another extended primer which is [a] complementary to [sequence copy of] said template [second] other strand.

12. (Currently Amended): The process as claimed in claim 3, wherein said non-nucleotide carrier macromolecule is bound to a solid support.

13. (Currently Amended): The process as claimed in claim 8, further comprising using a second primer wherein said second primer is extended in said amplification [procedure which] and said second primer is also bound to a carrier macromolecule.

14. (Currently Amended): The process as claimed in claim 10, wherein [said another primer] one of said at least two other primers which is ligated by said ligase is also bound to a carrier macromolecule.

16. (Currently Amended): The process as claimed in claim [15] 11, wherein said extension of [one of the primers] first primer or the second primer is conducted *in situ* in a biological sample.

20. (Currently Amended): A method of detecting a nucleic acid sequence in a sample, [comprising contacting said sample with a probe under hybridization conditions, wherein said probe comprises an extended primer having a sequence complementary to said sequence to be detected and wherein said probe has been made according to the method of claim 17 and further wherein said sequence is said template in the method of claim 17] comprising:

providing a primer bound to a non-nucleotide carrier macromolecule via one or more moieties derived from divinyl sulfone located on the non-nucleotide carrier macromolecule, wherein the non-nucleotide carrier macromolecule is a dextran;

hybridizing the bound primer to a portion of the target nucleic acid sequence;

extending the bound primer to form an extended primer which replicates from the target nucleic acid sequence to form an amplified probe that is complementary to the target nucleic acid sequence;

hybridizing the amplified probe to the target nucleic acid sequence in the sample; and

detecting a hybrid formed between the amplified probe and the target nucleic acid sequence to detect the target nucleic acid sequence in the sample.

23. (Currently Amended): A process for [the] replication of a nucleic acid template comprising:

providing a primer being bonded to a carrier macromolecule which is a dextran;

hybridizing the bound primer to said template; and

extending said bound primer to form an extended primer which replicates from said template,

wherein said primer is bound to said carrier macromolecule via one or more moieties derived from divinyl sulphone,

at least one of the moieties is attached to the carrier macromolecule by a covalent linkage formed between one of the two vinyl groups of [a] the divinyl sulphone molecule of the at least one of the moieties [moiety] and a reactive [functionality] group on the carrier macromolecule, and

at least one of the moieties is attached to the primer by a covalent linkage formed between one of the two vinyl groups of [a] the divinyl sulphone molecule of the at least one of the moieties [moiety] and a reactive group [functionality] on the primer.

25. (Currently Amended): The process of claim 23, wherein said dextran in its free state is substantially linear and substantially uncharged [unchanged] at a pH in the range of 4 to 10.

30. (Currently Amended): The process of claim 23, wherein said template is a double stranded template and is denatured to single stranded form, said dextran-bound primer is complementary in sequence to a region of [a first] one of the template strands and a second primer is provided which is complementary in sequence to a region of the other strand of the template, [which] and the second primer is also extended so as to form a complementary sequence copy of said template [second] other strand.

32. (Currently Amended): The process of claim 23, wherein said extension of the primer is conducted *in situ* [in situ] in a biological sample.

3. The following is an examiner's statement of reasons for allowance:

Claims 1, 3-17, 20, 23, 25, 26, 28-33, and 35-38 are allowable in light of the applicant's amendments filed on March 29, 2007 and the examiner's amendments. The rejections under 35 U.S.C 112, first and second paragraphs and 35 U.S.C 103 have been withdrawn in view of applicant's amendments filed on March 29, 2007 and the examiner's amendments. The closest prior art in the record are Gold *et al.,* (US Patent No. 6,011,020, filed on May 4, 1995) and Campbell (US H1398, published on January 3, 1995). These prior art in the record do not teach or suggest the primer recited in claims 1, 20, and 23 and the first primer recited in claim 3 (see pages 9 and 10 applicant's remarks filed on September 14, 2006). These prior art either alone or in combination with the other art in the record do not teach or reasonably suggest a process for amplification of a nucleic acid template, a method of detecting a target nucleic acid sequence in a sample, and a process for replication of a nucleic acid template which comprise all of the limitations recited in claims 1, 3, 20, and 23.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, .1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

May 11, 2007

FRANK LU
PRIMARY EXAMINER